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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,056	08/28/2001	Matthew M. Morrison	4002-2817	6549

7590 07/09/2004

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EXAMINER

ROBERT, EDUARDO C

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/941,056

Applicant(s)

MORRISON ET AL.

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/2/2004 & 4/22/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-78 is/are pending in the application.
- 4a) Of the above claim(s) 40-68 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 69-73 is/are allowed.
- 6) ☒ Claim(s) 35, 38, 74 and 77 is/are rejected.
- 7) ☒ Claim(s) 36, 37, 39, 75, 76 and 78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicants once again traverse to the restriction requirement and the examiner once again acknowledged the traversal. However, the ground(s) of the traversal were not persuasive (see Office Action mailed on October 14, 2003). It is noted that claims 40-68 were withdrawn from further consideration (see Office Action mailed on October 14, 2003) and they are still withdrawn. Furthermore, the requirement was made **FINAL** in the Office Action of October 14, 2003.

Terminal Disclaimer

The terminal disclaimer filed on January 20, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patents 6,280,445; 6,315,779 and application no. 09/978,932 (now Patent No. 6,689,133) has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Lin (U.S. Patent 5,582,612).

Lin discloses an orthopedic implant comprising a base member, e.g. 150', with lower surface, upper surface and at least one aperture (see Figure 3a). The implant further comprises a support or stabilizer, e.g. 610, having an opening and wherein the support or stabilizer is adjacent to the base member in one of an infinite number of positions wherein the opening communicates with the at least one aperture of the base member. The implant also has a fixation member 500 having a first portion 510, a second threaded portion 520, and an intermediate diametrically enlarged portion 530. The fixation member extends through the support or stabilizer and the base member so that the enlarged portion contacts the support or stabilizer (see Figures 3a-3c). A washer 640 having a rounded top is around the second threaded part of the fixation member (see Figure 3c). A nut 650 is threaded onto the second threaded part of the fixation member (see Figure 3c).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (U.S. Patent 5,582,612) in view of Devlin et al. (U.S. Patent 3,742,583).

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Lin discloses the claimed invention except for the nut including a break-off portion.

Devlin, et al. teach to provide a nut with a break-off portion in order to prevent that the torque is exceed when installing the nut (see col. 1, lines 25-45 and lines 64-67). It would have been obvious to one skill in the art at the time the invention was made to construct the implant of Lin with the nut having a break-off portion in view of Devlin et al., in order to prevent that the nut is over torque.

Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (U.S. Patent 5,582,612).

Lin discloses the claimed invention except of the intermediate diametrically enlarged portion being round. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct implant of Lin with the intermediate enlarged portion being round, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose preventing passage of the enlarged portion through the opening of the support or stabilizer. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (U.S. Patent 5,582,612), as applied to claim 74, and further in view of Devlin et al. (U.S. Patent 3,742,583).

Lin, as applied to claim 74, discloses the claimed invention except for the nut including a break-off portion. Devlin et al. teach to provide a nut with a break-off portion in order to prevent that the torque is exceed when installing the nut (see col. 1, lines 25-45 and lines 64-67). It would have been obvious to one skill in the art at the time the invention was made to construct

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the implant of Lin, as applied to claim 74, with the nut having a break-off portion in view of Devlin et al., in order to prevent that the nut is over torque.

Response to Arguments

Applicant's arguments filed on January 20, 2004 have been fully considered but they are not persuasive.

In response to applicant's argument that Lin does not show a stabilizer, it is noted that Lin clearly shows an element 610 which is considered a support since it supports element 620 as shown in Lin's Figures. Furthermore, what applicants call a stabilizer is element "26" which is also called a "support". Thus, applicant's element "26" is a support or stabilizer and clearly applicants use the terms interchangeably throughout applicant's specification (see applicant's specification, e.g. page 10, lines 11-12, and page 12, line 21). Furthermore, it is noted that something that support inherently stabilize and it appears that applicant's agree with this since the terms have been used interchangeably.

In response to applicant's argument that Lin's element 610 is not adjacent the part 150, it is noted that the Lin's Figures, e.g. Figures 3a-3c, clearly show that the element 610 is adjacent the part 150. It is noted that the term "adjacent" is define as "close to" by *The American Heritage Dictionary of the English Language, Third Edition 1992*.

In response to applicant's argument that the Lin and Devlin references are non-analogous, it is noted that it has been held that the determination that a reference is from a nonanalogous art is twofold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to

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the particular problem with which the inventor was involved. In re Wood, 202 USPQ 171, 174.

In this case, the references are reasonably within the field of the inventor's endeavor, i.e. an implant fixation device comprising parts, e.g. a nut, which require the application of torque without exceeding a predetermined amount of torque. The Lin reference is directed to an implant fixation device comprising parts, e.g. a nut, which require the application of torque and Devlinin is directed to the application of torque to parts such as a nut and how to prevent torque excess. Thus, clearly one looking into the field of inventor's endeavor would have considered art related to nuts and control of exceeding torque.

In response to applicant's argument that Lin discloses that "the grater the torque, the better the grip" and cited (see column 3, lines 66-67), it is noted that this is not in Lin column 3, lines 66-67. The following is a citation of col. 3, lines 65-67, "two knurled direction-adjusting washers 630,640, and a fastening nut 650".

In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin, 443 F.2d 1392; 170 USPQ 209 (CCPA 1971).

In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of

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primary and secondary references. In re Nomiya, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA) 1969. In this case, the Lin references discloses the claimed invention except for the nut including a break-off portion (see 102 and 103 rejections above) and Devlin teach to provide a nut with a break-off portion and the reason is to prevent that the torque is exceed when installing the nut (see col. 1, lines 25-45 and lines 64-67).

In response to applicant's argument that the Devlin devices does not suggest any basis for using its structure with the Lin device, it is noted that the test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art.

Allowable Subject Matter

Claims 69-73 are allowed.

Claims 36, 37, 39, 75, 76, and 78 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Examiner's Comments

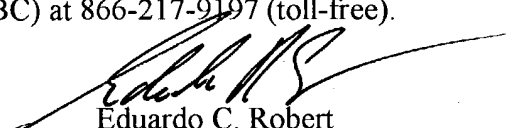
This application contains claims 40-68 drawn to an invention nonelected with traverse in the reply filed on July 28, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.